

REMARKS**Amendments to the Claims**

Claims 27-29 and 31-41 have been canceled. Claim 30 has been amended to incorporate Claim 36, which was dependent upon Claim 30. Support for this amendment is found throughout the specification, including originally-filed Claims 30 and 36. No new matter has been added by this amendment. Therefore, entry of the amendment into the application is respectfully requested.

Priority

The Examiner stated that the first line of the specification does not contain an updated status of the applications. Applicants note that the status of the related applications was updated in the Preliminary Amendment filed on July 16, 2004. The status of the related applications has not changed since that time.

The priority discussion is not relevant to the pending claims. On pages 2-4 of the Office Action, the Examiner indicated that priority applications do not support a claim limitation of 35 or more repeats, and do not support Claims 44-47, which the Examiner states are directed to the SCA2 gene. However, the pending examined claims are Claims 27-41, and these claims are method claims which do not contain a limitation of 35 or more repeats.

New Matter

The Examiner has rejected Claims 30-38 and 40 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 31-41 have been canceled. Claim 30 has been amended to incorporate Claim 36. In regard to the new matter rejection of Claim 36, the Examiner stated that “with respect to claim 36, the amendments [sic] provides....” (See Office Action at page 6). Applicant notes that a new matter rejection should not have been raised because no Amendments had been made to the claims. Claims 30 and 36 were part of the application as originally-filed. Claims as

filed in the original specification are part of the disclosure, and may even be added to any other part of the application without adding new matter. See M.P.E.P. §2163.06 (III).

Further, additional written description for amended Claim 30 is found in the specification, for example, at page 17, lines 22-28; page 26, line 27 to page 27, line 4; page 29, lines 2-20; Example 3 at pages 37-39, and Figures 3 and 6A. Further support is discussed below, in the remarks regarding enablement.

Withdrawal of the new matter rejection is respectfully requested.

Rejection of Claims 27-29, 39 and 41 under 35 U.S.C. §112, first paragraph

The Examiner rejected Claims 27-29, 39 and 41 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

While Applicants disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claims 27-29, 39 and 41, thereby obviating the rejection.

Rejection of Claims 27-41 under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 27-41 under 35 U.S.C. § 112, first paragraph as lacking enablement. Specifically, the Examiner stated that "the specification, while being enabling for detecting the presence of a CAG repeat in SEQ ID NO: 2, does not reasonably provide enablement for a method of detecting the presence of a CAG repeat region in the SCA2 gene on human chromosome 12q24.1 in an individual or a method of diagnosing SCA2 in a human sample by identifying the presence of a CAG repeat in a nucleic acid sample from chromosome 12q24.1 wherein the presence of a larger number of CAG repeats than exists in a normal population is indicative of SCA2."

While Applicant disagrees with the Examiner's position and reserve his rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claims 27-29 and 31-41. As discussed above, Claim 30 has been amended to incorporate Claim 36.

Claim 30, as amended, is enabled by the teachings of the specification. As amended, Claim 30 is directed to “a method of diagnosing spinocerebellar ataxia type 2 in a human nucleic acid sample comprising the steps of: amplifying said nucleic acid sample with a first primer and a second primer by polymerase chain reaction, wherein said first primer hybridizes to a region of nucleotides 303 to 657 of SEQ ID NO:2 and said second primer hybridizes to a region of nucleotides 723 to 890 of SEQ ID NO:2; obtaining an amplification product of said nucleic acid sample by said polymerase chain reaction; and measuring a number of CAG repeats in said amplification product by hybridizing a probe to said amplification product, wherein said probe has a sequence comprising greater than 22 CAG repeats, wherein a normal number of CAG repeats in said nucleic acid sample would be negative for spinocerebellar ataxia type 2.”

Support for Claim 30, as amended, is found throughout the specification. For example, support for “a method of diagnosing spinocerebellar ataxia type 2 in a human nucleic acid sample comprising the steps of: amplifying said nucleic acid sample with a first primer and a second primer by polymerase chain reaction, wherein said first primer hybridizes to a region of nucleotides 303 to 657 of SEQ ID NO:2 and said second primer hybridizes to a region of nucleotides 723 to 890 of SEQ ID NO:2” is found in the specification, for example, at page 17, lines 22-28; page 29, lines 6-14; and page 29, lines 24-30. Support for “obtaining an amplification product of said nucleic acid sample by said polymerase chain reaction” is found, for example, at page 29, lines 6-14. Support for “measuring a number of CAG repeats in said amplification product” is found, for example, at page 28, line 27 to page 29, line 2 and page 29, lines 12-14. Support for “hybridizing a probe to said amplification product” is found, for example, at page 17, lines 22-28; and page 29, lines 2-4. Support for “wherein said probe has a sequence comprising greater than 22 CAG repeats, wherein a normal number of CAG repeats in said nucleic acid sample would be negative for spinocerebellar ataxia type 2” is found in the specification, for example, at page 26, line 29 to page 27, line 4; page 29, lines 16-20; Example 3 and Figures 3 and 6A. In addition, support is found in originally-filed Claims 30 and 36.

The Background of the Invention teaches the presence of a class of genes that are correlated with the disease, spinocerebellar ataxia. The Examiner does not appear to dispute that the class is a recognized class within the art. The specification teaches that the gene responsible for the disease, SCA2, is a native gene. Thus, in the context of the claimed invention that detects

the presence of a gene in a human nucleic acid sample, that gene must be a native or naturally occurring gene. The specification teaches the specific location of the native or naturally occurring gene, i.e., human chromosome 12 at the q24.1 locus, and provides specific sequences (partial and full length) for the gene actually isolated from multiple human nucleic acid samples. Applicant demonstrated the reproducibility of the isolation and detection with several patients and controls. Thus, it is simply not seen why the specification is not enabling for the invention claimed in this application.

Applicant is not claiming the SCA2 gene itself or mutations or derivatives to the gene. Applicant is merely claiming diagnosing SCA2 in a human sample. The specification defines the gene by its function (pages 2-6), location (page 9), distinctions on location from other family members (pages 8-9) and partial and full length sequences (the Figures and Sequence Listing). No more is required. As noted by the Examiner, the level of skill in the art is deemed to be high.

The Examiner states that the practice of the invention encompasses sequences that have not been taught or described in the specification. (See Office Action at page 12). Again, the rejection is not understood. Nowhere in patent law does it state that a specification which embraces the use of novel products is not enabling and/or that a specification must specifically describe all possible embodiments. The specification must teach the person of ordinary skill in the art how to practice the invention, absent undue experimentation.

The invention is directed to a method of detecting a CAG repeat in a gene called SCA2, located at a specific site on chromosome 12 in a human sample and correlating the result with the disease, spinocerebellar ataxia. Applicant has disclosed a sequence with thousands of basepairs which can be used to make and use in a nearly infinite number of primers, with an exceedingly high degree of predictability. Such a specification is enabling for the invention claimed.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 27-29 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 27-29 under 35 U.S.C. § 112, second paragraph as being indefinite.

While Applicant disagrees with the Examiner's position and reserves his rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claims 27-29, rendering this rejection moot.

Rejection of Claim 39 under 35 U.S.C. § 102(a)

The Examiner has rejected Claim 39 under 35 U.S.C. § 102(g) as being anticipated by Trotter *et al.* (*Nature*, Vol. 378, pages 403-406, November 1995).

While Applicant disagrees with the Examiner's position and reserve his rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claim 39, rendering this rejection moot.

Rejection of Claims 27-35 and 37-41 under 35 U.S.C. § 102(g)

The Examiner has rejected Claims 27-35 and 37-41 under 35 U.S.C. § 102(g) as being anticipated by Tsuji *et al.* (U.S. Patent No. 6,251,589).

While Applicant disagrees with the Examiner's position and reserve his rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claims 27-29 and 31-41. Claim 30 has been amended to incorporate Claim 36, which was dependent upon Claim 30. Support for this amendment is found, for example, in originally-filed Claims 30 and 36. Claim 36 is not subject to this rejection, and the elements of Claim 30, particularly as amended, are not disclosed in the reference. Therefore, the reference does not anticipate amended Claim 30. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 27-29, 39 and 41 under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 27-29, 39 and 41 under 35 U.S.C. 103(a) as being unpatentable over Trotter *et al.* (*Nature*, Vol. 378, pages 403-406, November 1995) in view of either Filla (*Neurology*, Vol. 45, pages 793-796, April 1995) or Pulst *et al.* (*Nature Genetics*, Vol. 5, pages 8-10, 1993).

While Applicant disagrees with the Examiner's position and reserve his rights to file continuing or divisional applications to pursue these claims, in order to expedite prosecution, Applicant has canceled Claims 27-29, 39 and 41.

Rejection of Claims 27-41 under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has rejected Claims 27-41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of U.S. Patent No. 6,673,535.

Applicant notes this rejection and will file a terminal disclaimer, if appropriate, upon indication that the only remaining rejections are the Double Patenting rejections.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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